

PCT
JC06 Rec'd PCT/PTO 02 SEP 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Evans, J.

Serial No. 10/525,440

Filed: February 24, 2005

For: METHOD FOR THE PREVENTION AND
TREATMENT OF ATHEROSCLEROSIS

Art Unit: _____

Examiner: _____

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR 1.97

Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).

2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.

4. Pursuant to 37 C.F.R. 1.98 (a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

MERCK & CO., INC.

By Cherie A. Winkler Date 8/31/05

INFORMATION DISCLOSURE STATEMENT

5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

| RELATED APPLICATION | | |
|---------------------|-------------|------------|
| U. S. SERIAL NUMBER | FILING DATE | MERCK CASE |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

If this is inconvenient, additional copies will be submitted upon request.

6. In accordance with 37 C.F.R. 1.97, (check one)

- ☐ the attached information is filed within three months of the filing date of the captioned case.
- ☒ the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits.
- ☐ the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action or Notice of Allowance. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).
- ☐ the undersigned certifies that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.
- ☐ the undersigned certifies that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of this Statement.

Respectfully submitted,



By: Carol S. Quagliato

Attorney _____ For Applicant(s)

Reg. No. 35,330

MERCK & CO., INC.

Patent Dept., RY60-30

P.O. Box 2000

Rahway, N.J. 07065-0907

(732)594-3809

Date: August 31, 2005

COMPLETE IF KNOWN

| | |
|---------------------------|------------|
| Application Number | 10/525,440 |
|---------------------------|------------|

| | |
|--------------------|-------------------|
| Filing Date | February 24, 2005 |
|--------------------|-------------------|

| | |
|-----------------------------|-----------|
| First Named Inventor | Evans, J. |
|-----------------------------|-----------|

Group Art Unit

Examiner Name

| | |
|------------------------|---------|
| Attorney Docket Number | 21217YP |
|------------------------|---------|

(use as many sheets as necessary)

Sheet

1

of

3

[illegible][illegible]Date
Considered

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

SEND TO: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450. Computer generated form "IDS Form" (IDS Folder), Merck & Co., Inc., -7/12/2005

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE

STATEMENT BY APPLICANT

(use as many sheets as necessary)

2

of

3

COMPLETE IF KNOWN

Application Number 10/525,440

Filing Date February 24, 2005

First Named Inventor Evans, J.

Group Art Unit

Examiner Name

Attorney Docket Number 21217YP

NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No. | Include name of the author, title, date, page(s), volume-issue number(s) and place of publication. |
|--------------------|----------|--|
| | A | Mehrabian et al., "Identification of 5-Lipoxygenase as a Major Gene Contributing to Atherosclerosis Susceptibility in Mice", Circulation Research, pp. 120-126 (July 26, 2002) |
| | B | Mehrabian et al., "Genetic Locus in Mice Blocks Development of Atherosclerosis Despite Extreme Hyperlipidemia", Circulation Research, pp. 125-130 (July 20, 2001) |
| | C | Allen et al., "Differential Leukotriene Constrictor Responses in Human Atherosclerotic Coronary Arteries", Circulation, Vol. 97(24), pp. 2406-2413 (1998) |
| | D | Prasit et al., "A new class of leukotriene biosynthesis inhibitor: the development of MK-0591", Journal of Lipid Mediators, Vol. 6, pp. 239-244 (1993) |
| | E | Young et al., "Discovery of inhibitors of the 5-lipoxygenase activating protein (flap)", Journal of Lipid Mediators, Vol. 6, pp. 233-238 (1993) |
| | F | Brideau et al., "Pharmacology of MK-0591 (3-[1-(4-chlorobenzyl)-3-(t-butylthio)-5-(quinolin-2-yl-methoxy)-indol-2-yl]-2,2-dimethyl propanoic acid), a potent, orally active leukotriene biosynthesis inhibitor", Can. Journal Physiol. Pharmacol., Vol. 70, pp. 799-807 (1992) |
| | G | Charleson et al., "Characterization of a 5-Lipoxygenase-Activating Protein Binding Assay: Correlation of Affinity for 5-Lipoxygenase-Activating Protein with Leukotriene Synthesis Inhibition", Molecular Pharmacology, Vol. 41, pp. 873-879 (May 1992) |
| | H | Mancini et al., "5-Lipoxygenase-Activating Protein Is the Target of a Novel Hybrid of Two Classes of Leukotriene Biosynthesis Inhibitors", Molecular Pharmacology, Vol. 41, pp. 267-272 (Feb. 1992) |
| | I | Evans et al., "5-Lipoxygenase-Activating Protein Is the Target of a Quinoline Class of Leukotriene Synthesis Inhibitors", Molecular Pharmacology, Vol. 40, pp. 22-27 (July 1991) |
| | J | Reid et al., "Correlation between expression of 5-lipoxygenase-activating protein, 5-lipoxygenase, and cellular leukotriene synthesis", J. Biol. Chem., Vol. 265(32), pp. 19818-23 (1990) |
| | K | Dixon et al., "Requirement of a 5-lipoxygenase-activating protein for leukotriene synthesis", Nature, Vol. 343, No. 6255, pp. 282-284 (1990) |
| | L | Miller et al., "Identification and isolation of a membrane protein necessary for leukotriene production", Nature, Vol. 343, No. 6255, pp. 278-281 (1990) |
| | M | Datta et al., "Peptido-Leukotrienes Are Potent Agonists of von Willebrand Factor Secretion and P-Selectin Surface Expression in Human Umbilical Vein Endothelial Cells", Circulation, Vol. 92, No. 11, pp. 3304-3311 (1995) |
| | N | Huang et al., "Endothelial Cell Cytosolic Free Calcium Regulates Neutrophil Migration across Monolayers of Endothelial Cells", J. Cell Biol., Vol. 120, No. 6, pp. 1371-1380 (1993) |
| | O | Heimburger et al., Effects of leukotriene C4 and D4, histamine and bradykinin on cytosolic calcium concentrations and adhesiveness of endothelial cells and neutrophils", Clin. Exp. Immunol., 103, pp. 454-460 (1996) |

Examiner Signature

Date Considered

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

SEND TO: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

Computer generated form "IDS Form" (IDS Folder), Merck & Co., Inc., -7/12/2005

COMPLETE IF KNOWN

| | |
|---------------------------|------------|
| Application Number | 10/525,440 |
|---------------------------|------------|

| | |
|--------------------|-------------------|
| Filing Date | February 24, 2005 |
|--------------------|-------------------|

| | |
|-----------------------------|-----------|
| First Named Inventor | Evans, J. |
|-----------------------------|-----------|

Group Art Unit

Examiner Name

Attorney Docket Number 21217YP

3

of

3

Examiner
Initials*Cite
No.

Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.

P

McIntyre et al., "Leukotrienes C4 and D4 stimulate human endothelial cells to synthesize platelet-activating factor and bind neutrophils", Proc. Natl. Acad. Sci. USA, Vol. 83, pp. 2204-2208 (1986)

Q

Spanbroek et al., "The Potential Role of Antileukotriene Drugs in Atherosclerosis", *Drug News Perspect*, Vol. 16(8), pp. 485-489 (2003).

R

Spanbroek et al., "Expanding expression of the 5-lipoxygenase pathway within the arterial wall during human atherogenesis", PNAS, vol. 100, No. 3, pp. 1238-1243 (2003)

**Examiner
Signature**

Date
Considered

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

SEND TO: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

Computer generated form "IDS Form" (IDS Folder), Merck & Co., Inc., -7/12/2005